NWX-DISEASE CONTROL & PREVENTION

Moderator: Dale Babcock
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11:00 am CT

Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen only mode. During the question and answer session you may press star 1 on your touchtone phone if you would like to ask a question.

Today's conference is being recorded if you have any objections you may disconnect at this time. I'd now like to turn the call over to Dr. Andrew Kroger, you may begin.

Andrew Kroger: Thank you very much. Welcome to current issues in immunization net conferences. I'm Andrew Kroger; I'm a medical officer in the Immunization Services Division of the National Center for Immunization and Respiratory Diseases or NCIRD at the CDC and I'll be the moderator for today's session.

To participate in today's program you need a telephone connection and a separate internet connection. The learning objectives for this session are: to describe an emerging immunization issue;
to be able to list a recent immunization recommendation made by the Advisory Committee on Immunization Practices or ACIP; to locate recourses

relevant to current immunization practice; and to obtain, assess and apply patient information to determine the need for immunization.

Today is August 19, 2015. Our topic for today's net conference is DTaP/Tdap vaccines. I'm pleased to introduce Dr. Candice Robinson a medical officer in the Communication and Education Branch in the Immunization Services Division in NCIRD at the CDC.

She will discuss these vaccines as presented in the CDC textbook, Epidemiology and the Prevention of Vaccine-Preventable Diseases also known as the Pink Book whose 13th edition was published this year.

A question and answer session will follow today's presentation and we will offer another question and answer session on Thursday, August 27 at 10:00 am Eastern time for those who could not attend today's session, or did not have time to ask a question.

Please make a note of the following information, if you have technical trouble please dial star 0 on your telephone. If you'd like to ask a question when we get to that segment please press star 1 on the phone.

Continuing education or CE credit is available only through the CDC/ATSDR training and continuing education online system at www2A.CDC.gov/TCEonline/. CE credit for this session today expires on September 21, 2015.

CDC, our planners and our presenters wish to disclose that they have no financial interest or other relationships with the manufacturers of commercial products, suppliers of commercial services or commercial supporters.

Presentations will not include any discussion of the unlabeled use of a product or a product under investigational use with the exception of Dr. Robinson's discussion of the use of DTaP and Tdap vaccines in a manner recommended by the Advisory Committee on Immunization Practices but not approved by the Food and Drug Administration.

CDC does not accept any commercial support so I will now turn the microphone over to Dr. Robinson, you may begin.

Candice Robinson: The content for today's presentation can be found in the Pink Book. Content regarding Diphtheria can be found starting on pages 107, Pertussis content starting on page 261, and Tetanus content starting on page 341.

Diphtheria is a toxin-mediated disease it can infect almost any mucus membrane and is classified based on the site of infection. Most commonly it infects the nasal pharynx and causes an exudate that within two to five days may form an adherent membrane on the pharynx and tonsils which can lead to respiratory obstruction.

As they grow the bacteria produce a toxin that is absorbed into the bloodstream. The absorbed toxin causes most of the complications of Diphtheria such as myocarditis, or inflammation of the heart, and neuritis which leads to abnormal nerve conduction.

Diphtheria results in death in 5 to 10% of cases. This picture depicts the tough adherent membrane in the back of the throat that can occlude the airway. It can cause serious bleeding with efforts to remove it.

This chart shows the number of diphtheria cases reported annually in the U.S. from 1990 through 2011. Fewer than five cases of diphtheria have been reported each year in the U.S. since 1980.

Since 2000 a total of about five cases have been reported. Most cases have been reported in adults. There is no current geographic concentration of cases observed in the U.S.

The disease is transmitted mainly person to person via respiratory tracts and rarely through skin or fomites. The majority of cases reported are among persons 25 years and older.

Many physicians have never seen a known case of diphtheria. They may not even consider the diagnosis in a patient with a membranous pharyngitis. Laboratories do not test for it unless a diphtheria culture is specifically requested.

So the organism is probably still out there, we just don't see it because we're not looking hard enough. The greatest risk of infection is during travel outside of the U.S. where diphtheria is more prevalent.

In 2003 there was a case where a 63 year old man who had never been vaccinated against diphtheria visited Haiti and returned to the U.S. with a sore throat and difficulty swallowing.

He was initially treated for strep throat. A few days later he returned to the ER worse and he later died from cardiac complications. Based on the patient’s travel to a country where diphtheria is epidemic, the pattern of illness, and positive PCR results, his illness was consistent with a confirmed case of respiratory diphtheria.

Up to 60% of adults have an inadequate protective level of circulating antitoxin.

Tetanus is an acute often fatal disease caused by a toxin produced by the bacterium *Clostridium tetani*.

The bacteria and its spores are found everywhere in the world that has dirt and animal feces and may persist for months to years. We will never eradicate tetanus. One of the toxins tetanospasmin blocks the impulses in certain nerves which can lead to unopposed muscle contractions and spasms.

It is one of the most potent toxins known to man. The most common form is generalized tetanus. The disease usually presents with a descending pattern. The first sign is trismus or lockjaw followed by stiffness of the neck, difficulty swallowing and rigidity and of abdominal muscles.

The complications of tetanus include spasms of the respiratory muscles, which can lead to respiratory arrest. Muscle spasms can be so severe they break bones. If a person doesn't die as a direct result of the tetanus they may die from the complications that come along with a long hospitalization and recovery.

This chart shows the number of reported tetanus cases from 1990 to 2012. There has been an overall decline in cases since 1990. During 2001 through 2008, the last years for which the data has been compiled, a total of 233 tetanus cases were reported, an average of 29 cases per year.

Among the 197 cases with known outcomes the case fatality rate was 13%. Age of onset was reported for all 233 cases. The median age was 49 years

with a range of 5 to 94 years. Forty-nine percent of cases were amongst persons 50 years of age or older.

Among the reported tetanus cases, 15% reported to have diabetes, 15% were IV drug users, 72% reported an acute wound such as a puncture or a contaminated wound, and 13% reported a chronic wound before disease onset such as a diabetic ulcer or a dental abscess.

This is a picture of a child with generalized tetanus. The exotoxins are causing his back to curve giving his body this contorted appearance.

We will spend a little more time on pertussis.

Pertussis is a highly contagious respiratory infection caused by the bacterium *Bordetella pertussis*. Disease onset is insidious with nonspecific cough and minimal fever. The incubation period is five to ten days.

There are three stages to pertussis. Catarrhal stage is characterized by runny nose, sneezing, low grade fever and mild cough, and presents much like the common cold. This is the stage where maximum communicability occurs.

During the paroxysmal stage the diagnosis is usually suspected because of the characteristic bursts of rapid coughs because the person is unable to get rid of thick mucus from the trachea and bronchi.

This is then followed by a characteristic whoop. An example of this can be seen in the video clip distributed with the log-in information email. This video shows an infant with Pertussis and demonstrates the bursts of cough and the whoop.

Patients can turn blue and children can look very ill. The most common complication reported is secondary bacterial pneumonia. Other complications include seizures and approximately 16% required hospitalization.

Finally, during the convalescent stage cough is less paroxysmal and gradually disappears. This phase can last weeks to months. In 2008 through 2011 a total of 72 deaths from pertussis were reported to CDC.

Of the 72 pertussis related deaths, 60, or 83% were infants younger than three months of age. This graph illustrates the number of pertussis cases reported to CDC from 1922 to 2014.

Following the introduction of pertussis vaccines in the 1940's when case counts frequently exceeded 100,000 cases per year, reports declined dramatically to fewer than 10,000 by 1965.

Notice that cyclic peaks occur every two to five years even as the incidence was falling, as well as the increase in cases since 2003. Recent cases peaked with over 40,000 cases in 2012 and over 28,000 in each of 2013 and 2014.

Why? Immunity from acellular pertussis vaccines wanes after a dose within five years - and within five years after the DTaP series. And in less time after one dose of Tdap.

This graph shows reported pertussis incidence per 100,000 persons by age group in the United States from 1990 to 2013. Infants aged less than one year, who are at greatest risk for severe disease and death, continue to have the highest reported rate of pertussis.

School-aged children 7 to 10 years continue to contribute a significant proportion of pertussis related cases. So then why do adolescents and adult need pertussis vaccine?

In 2013 and 2014 there were over 28,000 cases of pertussis reported in the U.S. Many of these cases were in persons aged 11 and older. In fact this age group accounted for over 50% of all cases in 2014.

Disease in adults and adolescents is often milder than disease in infants and children. Infection may be asymptomatic or present as classic pertussis. Even person with mild disease may transmit the infection.

Additionally, older persons are often a source of infection for children. According to a 2007 study a household contact, such as a parent or sibling, was the source of infection for an infant with pertussis over 70% of the time.

Non-household contacts, such as a grandparent or friend, was a source of infection nearly 30% of the time. Pertussis in adolescents and adults is not without consequence. Illness can have a prolonged cough that can persist for three months or longer.

Post-tussive vomiting may occur after a severe paroxysm of cough. Adults and adolescents may also develop complications of pertussis such as difficulty sleeping, urinary incontinence, pneumonia and rib fracture.

Adults and adolescents often have multiple medical visits and may undergo extensive medical evaluation for the persistent cough before pertussis is considered as the diagnosis and they may miss school or work.

In summary diphtheria, tetanus and pertussis are diseases that can occur throughout the lifetime and vaccination needs to occur throughout the lifetime to be protected. Now let's shift our focus to the vaccines.

DTaP vaccine, that's big D, big T, little a, big P, is a pediatric formulation. DTaP is approved for children six weeks through six years of age, that is up until the seventh birthday. DTaP should not be administered to anyone seven years or older.

DTaP contains the same amount of Diphtheria and Tetanus toxoids as pediatric DT vaccine. As of April 2012 there are two pediatric DTaP products available in the United States, DAPTACEL and Infanrix.

These vaccines have been studied in either blinded cohort studies or in case-control studies. They have an estimated three dose efficacy of 80 to 85% against typical pertussis disease.

Although the vaccines contain different formulations, there is no clear evidence that one is significantly more effective than the other. As a result neither ACIP nor AAP has stated a preference for one of these vaccines.

In addition, there are four combination vaccines that contain DTaP. In December 2002 the Food and Drug Administration approved a new combination vaccine that contains DTaP, inactivated polio and hepatitis B.

The vaccine is called Pediarix and is produced by GlaxoSmithKline. The DTaP component is Infanrix and the Hep B component is Engerix-B which were previously licensed in the U.S.

Pediarix is approved for the first three doses of the DTaP and IPV series which are usually given at about two, four and six months of age. It is not approved for the fourth of fifth doses of the DTaP series.

The minimum age for the first dose of Pediarix is six weeks. It cannot be used for the birth dose of the hepatitis B series. The vaccine is not approved for use in children seven years of age or older.

Pediarix can be given to infants who received a birth dose of hepatitis B vaccine. These infants would receive a total of four doses of hepatitis B vaccine.

An important factor to remember about Pediarix, and any other combination vaccine for that matter, is that the minimum interval between doses are dictated by the single antigen with longest minimal intervals.

Therefore Pediarix minimum intervals are determined by the hepatitis B component. As with hepatitis B vaccine, the minimal interval between the first two doses of Pediarix is four weeks.

The third dose must be administered at least eight weeks after the second dose and should follow the first dose by at least 16 weeks. Hepatitis B will be covered in a future module.

The second combination vaccine that contains DTaP is Pentacel. Produced by Sanofi Pasteur the vaccine contains DTaP, inactivated Polio and Hib vaccine. Pentacel is FDA approved for doses one through four of the DTaP series among children six weeks through four years of age, that is, up to the fifth birthday.

Pentacel should not be used for the fifth dose of the DTaP series or for children five years or older. Pentacel must be reconstituted prior to administration. Lyophilized ActHIB is reconstituted with liquid DTaP, IPV solution. You should only use the manufacturer's supply vaccine diluent.

The last two combinations vaccines are a combination of DTaP and inactivated polio vaccine. Kinrix, manufactured by GlaxoSmithKline and Quadracel manufactured by Sanofi Pasteur.

Each are approved for use in children four through six years of age and only as the fifth dose of the DTaP series. They should not be used for doses one through four or for children younger than four years of age.

This table is a summary of all of the DTaP containing vaccines. Be sure to administer the correct DTaP vaccine based on the age of the child and the DTaP dose you are administering. There are a few data on the interchangeability of the pediatric DTaP vaccines.

ACIP recommends that whenever feasible the same DTaP vaccine should be used for all doses of the series. If the brand of vaccine used for earlier doses is not known or not available then any brand may be used to complete the series.

Now we will discuss the primary DTaP schedule. DTaP vaccine is recommended for all infants and children. A primary series in infancy is four doses beginning at about two months of age.

The first three doses are usually separated by two months. The fourth dose should follow the third dose by at least six months and should be given at 15 to 18 months of age. If an accelerated schedule is needed the first dose can be

given at six weeks of age with the second and third doses given at four week intervals.

DTaP can and should be given simultaneously with all other childhood vaccines the child needs at these visits, with a separate syringe and at a separate site of course. We receive many questions about the appropriate age for the fourth dose of DTaP.

The fourth dose of all brands is licensed and recommend by ACIP to be given at 15 to 18 months of age. But ACIP also states that the fourth dose may be given earlier than 15 months in certain circumstances.

Specifically, the fourth dose may be given earlier than 15 months of age if the child is at least 12 months of age, and it's been at least six months since the third dose of Pertussis vaccine, and in your opinion the child is unlikely to return for an additional visit at 15 to 18 months of age.

The age and timing of the dose at school entry can also be confusing. A fifth dose of DTaP at four through six years of age is recommended when the fourth dose is given before age four years.

This final dose in the DTaP series should be administered no earlier than the fourth birthday and at least six months after the previous dose. You will encounter children who have received all five doses of DTaP prior to the fourth birthday.

A booster dose of pertussis vaccine prior to school entry is important to maintain pertussis immunity throughout the school years. ACIP recommends that children who received the fifth dose prior to four years of age receive an

additional dose of DTaP after age four and at least six months after the previous dose.

Diphtheria and tetanus toxoids or DT vaccines is approve for use in children six weeks through six years of age. It is given as a three or four dose series depending on the age of the child at the time of the first dose.

Pediatric DT is used for children with a valid contraindication to Pertussis vaccines. If the child was younger than 12 months when the first dose of DT was administered the child should receive a total of four primary doses. If the child was 12 months of age or older when the first dose was administered three doses complete the primary series.

These next slides will discuss first contraindications and then precautions to administering DTaP. These are the true contraindications to receiving DTaP vaccines, severe allergic reaction following prior dose and encephalopathy not due to another cause within seven days of vaccination.

Of note encephalopathy, though reported previously with the use of whole-cell vaccines, has not been associated with acellular vaccines. As with all other vaccines moderate or severe acute illness is a precaution for DTaP vaccination and vaccination should be deferred until the acute condition improves.

If any of the next four events occur following pertussis vaccination then additional doses of pertussis generally should not be given: temperate to 105 within 48 hours of vaccination with no other identifying cause, collapse or shock-like state within 48 hours, persistent inconsolable crying lasting more than three hours, or convulsion with or without fever occurring within three days of vaccination.

All of these precautionary conditions have been reported following both whole-cell and acellular pertussis vaccines. While they're scary they do not result in permanent injury nor do they predict future reactions.

DTaP has not been associated with any permanent brain injury. If one of these reactions occurred following a dose of any type of pertussis vaccine you wouldn't normally give additional doses. The series would be completed with pediatric DT.

Remember that precautions require your judgement. You need to determine if the benefit of pertussis vaccine outweighs the risk of a recurrent adverse reaction, if so you may choose the vaccine.

For example, one of your patients is a normal six month old who had a fever of 105 the day after his second DTaP. Now there's a community-wide pertussis outbreak going on. You may choose to vaccinate this child because the risk from the disease exceeds the risk from the vaccination.

As with all injected vaccines DTaP may cause the following adverse reactions. Local reactions have bene reported in 30 to 50% of children after the first three doses. Fevers in 3 to 5% of children are usually self-limited and can be managed with acetaminophen or ibuprofen. More severe reactions are not common.

Local and systemic reactions like fever are more common after the fourth and fifth doses. The cause and frequency of these unusual reactions is not known but they appear to be self-limited and resolve without sequelae.

There have also been reports of swelling of an entire limb following the fourth or fifth dose of DTaP vaccine. Parents should be informed of the increase risk in local reactions that has been reported following the fourth and fifth doses of DTaP.

ACIP recommends that a history of extensive limb swelling after the fourth dose should not be considered a contraindication to receipt of the fifth dose at school entry. Now we're going to discuss Tdap and Td vaccines.

Tdap vaccines, that's big T, little d, little a, little p, is the acellular pertussis vaccine for adolescents and adults. The big T and little d should help remind you that these are vaccines for older persons like adult Td.

Both Tdap vaccines are approved by the Food and Drug Administration for a single booster dose for persons who have completed the recommended childhood DT or DTaP vaccination series.

Tdap contains less diphtheria toxoid in acellular pertussis antigens than DTaP. BOOSTRIX is approved for persons ten years of older. Adacel is approved for persons 10 through 64 years of age.

A single dose of Tdap is routinely recommended for adolescents 11 through 18 years of age, adults 19 through 64 years of age, and adults 65 years of age and older who have or anticipate having close contact with an infant less than 12 months of age.

Onthe Tdap row in the vaccine schedule, you will notice that Tdap may be used in children aged seven to ten years. The current FDA approved minimum age for Tdap vaccine is ten years for BOOSTRIX and Adacel.

The maximum approved age for all DTaP vaccines is six years. No pertussis containing vaccine is approved by the FDA for children seven through nine years of age. ACIP recognized that some children seven through nine years of age need pertussis vaccine; in particular those who have not received a complete series of DTaP before their seventh birthday.

ACIP recommends that children seven through ten years of age who are not fully vaccinated against pertussis, and who do not have a contraindication to pertussis vaccine, should receive a single dose of Tdap to provide protection against pertussis.

Either brand of Tdap may be used. Tdap is recommended in this age group because of its reduced antigen content compared with DTaP resulting in lower risks for local adverse reactions.

After review of available data on safety and immunogenicity of pertussis vaccine among children seven through ten years of age ACIP voted to recommend off-label use of Tdap in this age group.

“Not fully vaccinated against pertussis” is defined as having received fewer than four doses of DTaP, or having received four doses of DTaP but the last dose was prior to four years of age.

If additional doses of tetanus and diphtheria toxoid containing vaccines are needed then children seven through ten years of age should be vaccinated according to the catch-up schedule. Now to discuss Tdap and Td use in adults.

Administer Tdap to those 19 years of age and older who have not received Tdap or with unknown vaccination status. When feasible BOOSTRIX should

be used for adults 65 years of age and older because it is approved by the FDA for persons of this age.

However, either Tdap vaccine administered to a person 65 years of age or older provides protection. Td is routinely recommended for use every ten years following a dose of Tdap vaccine. Td is also approved for primary series doses.

All adolescents and adults should have documentation of having received a primary series of at least three doses of tetanus and diphtheria toxoids during their lifetime.

A person without such documentation should receive a series of three doses of tetanus and diphtheria toxoid containing vaccines. One of these doses, preferably the first, should be Tdap. The remaining two doses should be adult formulation Td.

Here is the preferred schedule, after the first Tdap dose, the second dose of Td should be administered at least four weeks after dose one. The third dose Td should be administered at least six months after dose two. Booster Td doses should be administered every ten years thereafter.

Comparing Tdap and Td; both can be used in person's age seven years and older. Most people will receive only one dose of Tdap in their lifetime but they will receive multiple doses of Td as a booster every ten years.

Now let's discuss Tdap in pregnant women. Tdap is recommended in pregnancy to provide the infant with protection from pertussis. ACIP recommends that providers of prenatal care implement a Tdap immunization program for all pregnant women.

Healthcare personnel should administer a dose of Tdap during each pregnancy irrespective of the patient's prior history of receiving Tdap. To maximize the maternal antibody response and passive antibody transfer to the infant, optimal timing for Tdap administration is between 27 and 36 weeks gestation.

Although Tdap may be given at any time during pregnancy. For women not previously vaccinated with Tdap, if Tdap is not administered during pregnancy, Tdap should be administered immediately postpartum.

Studies on the persistence of anti-Pertussis antibodies following a dose of Tdap show antibody levels in healthy non-pregnant adults peak during the first month after vaccination with antibody levels declining after one year.

The decline in antibody levels in pregnant women likely would be similar. Because antibody levels wane substantially during the first year after vaccination ACIP concluded a single dose of Tdap at one pregnancy would be insufficient to provide protection for subsequent pregnancies.

Remember, the baby's first dose of Pertussis vaccine is the one you give their mother. No study has assessed the safety of repeated doses of Tdap in pregnant women. Data is reassuring on two doses of Tdap.

Additionally, data and experience with tetanus toxoid vaccines suggest no excess risk of adverse events. Using data on the number of pregnancy the average women will have, it is estimated that only approximately 5% of women would receive four or more doses of Tdap in their lifetime.

CDC provides ongoing monitoring and assessment of the safety of Tdap vaccine use during pregnancy.

Now for another special population, healthcare personnel.

Healthcare personnel should receive a single dose of Tdap as soon as feasible if they have not previously received Tdap. This is regardless of the time since their most recent Td vaccination.

Priority should be given to vaccination of healthcare personnel who have direct contact with infants 12 months of age and younger. To prevent pertussis infection in infants assure that you and other staff in your facility have received Tdap.

Partner with clinicians who have access to families of infants to provide Tdap. Tdap is contraindicated for persons with a history of severe allergic reaction to a vaccine component or following a prior dose of vaccine.

Tdap is also contraindicated for persons with a history of encephalopathy not due to another identifiable cause occurring within seven days after administration of a pertussis containing vaccine.

Precautions to Tdap include a history of Guillain-Barré Syndrome within six weeks after a previous dose of tetanus toxoid containing vaccine. If a patient has a progressive neurologic disorder such as uncontrolled epilepsy or a progressive encephalopathy Tdap vaccination should be deferred until the condition has stabilized.

Persons with a history of severe local reaction, or Arthus reaction, following a prior dose of tetanus and/or diphtheria toxoid containing vaccine should generally not receive Tdap or Td vaccination until at least ten years have elapsed the last Td containing vaccine.

Moderate or severe acute illness is a precaution to vaccination. Persons for whom vaccinations is deferred because of moderate or severe acute illness should be vaccinated when their condition improves.

It is worth mentioning that some conditions that are precautions to the use of pediatric DTaP are not precautions to the use of the Tdap. ACIP believes that these conditions are unique to young children and are not expected to be an issue among adolescents or adults.

The most common adverse reactions following both brands of Tdap vaccine is a local reaction such as pain, redness or swelling at the injection site. Temperature of 100.4 or higher was reported by 1.4% of Tdap recipients and 1.1% of Td recipients.

Tdap recipients also reported a variety of nonspecific systemic events, such as headache, fatigue, and gastrointestinal symptoms. Local reactions, fever and nonspecific systemic symptoms occurred at approximately the same rate in recipients of Tdap when compared with a group that received Td without acellular pertussis vaccine.

No serious adverse events have been attributed to Tdap. Here's one consideration for choosing a Tdap injection site in adolescents, enhanced local reactions are associated with Meningococcal vaccines and Tdap so use separate limbs for these injections, if possible.

Here are some additional resources for Diphtheria, Tetanus and Pertussis as well as the DTaP and Tdap vaccine recommendations. There is a link to the CDC's pertussis and pregnancy webpage which provides resources for

discussing pertussis vaccine with pregnant patients, as well as the poster seen on the introductory pertussis and pregnancy slide.

And with that I will turn the session back over to Dr. Kroger.

Andrew Kroger: Thank you very much, Dr. Robinson. Now we're going to move to a question and answer session. While the queue fills I'm going to give you some information about continuing education.

Note that if you do have a question please dial star 1 to get in the queue for the operator and please be sure that your question is related to today's content.

We will have a recast of this program available on the internet on our website at www.CDC.gov/vaccine/ED/CIINC. This will be available the week of August 24, 2015. The slides will be on the website, as will the audio portion and other resource information.

For continuing education credit go to www2A.CDC.gov/TCEonline. The course number for this program is date specific and reads as follows, EC2064-081915. That last part is today's date August 19, 2015.

You will need this course number when completing CE requirements. You will also need the verification code which is DTAP7 with no space between the P and the 7. And this code applies to today's program only. So I'll repeat that verification code it's DTAP7.

CE credit for this program expires September 21, 2015. I will repeat this information at the end of question and answer period as well. So now I will turn it over to the operator, please let us have our participant ask the questions they wish to ask, operator?

Coordinator: Yes, at this time if you'd like to ask a question you may press star 1. Please remember to unmute your phone and record your first and last name clearly when prompted. And our first question comes from ().

(XXXX): Hello, thank you for the presentation. My question is, our first subset of healthcare workers were vaccinated with Tdap, it happened in 2006. And as we're beginning to look at 2016 right around the corner what do you think the recommendations will be for healthcare workers at that point?

Andrew Kroger: Candice?

Candice Robinson: Yes. So currently the recommendation is just for the healthcare providers to have one dose of Tdap vaccine. Currently there is not a recommendation for any further doses of Tdap vaccine.

However, at the ten year mark they should receive their boosters of Td vaccine but not Tdap per the current recommendation.

Andrew Kroger: Thank you very much, does that answer the question?

(XXXXX): Yes, well, do you see a new vaccine on the horizon knowing that this one probably hasn't been as efficient as we hoped it would be?

Candice Robinson: No future forecast in terms of what may be available in the future. We do not have any future forecast currently just the recommendations based on what we have which is one Tdap followed by a Td.

(XXXXX): Thank you.

Andrew Kroger: Thank you. We'll take the next question?

Coordinator: Next question comes from ().

Candice Robinson: Hi ().

(XXX): Yes, hi. I have a question about when we have cases of Pertussis in the home we had been asking them to have the household family contacts get vaccinated and/or chemoprophylaxis. Is that still the recommendation?

Candice Robinson: For household contacts of people with Pertussis you want to ensure that they are up to date on their vaccines per the current recommendations. If you have someone in the household who is not up to date you want to make sure that that person does get up to date on their vaccinations.

Chemoprophylaxis, I believe, is still recommended for household contacts of Pertussis cases as well. Currently it's only if they are not up to date on their vaccinations you definitely want to make sure that they do become up to date on their vaccinations at that time.

(XXX): Okay. Thank you.

Andrew Kroger: Yes, is there any follow-up question. If there any follow-up questions related to outbreak response you can always send a follow-up to NIPINFO and we'll, double-check the surveillance manual content on that.

(XXX): Thank you.

Andrew Kroger: We'll take the next question in the queue.

Coordinator: Next question comes from ().

(XXXX): Hi. My question has to do with international travelers of any age. Is there any consideration between Adacel and BOOSTRIX that would make one a choice over the other?

Candice Robinson: Currently we do not have any preference for Adacel or BOOSTRIX, one being preferred over the other, in the context of the current recommendations nor in the context of international travel.

(XXXX): Thank you.

Andrew Kroger: Thank you. We'll take the next question.

Coordinator: This question comes from ().

Andrew Kroger: Hi ()? I guess we're not hearing anything, operator. Can we take the next question in the queue? Well while we wait for another question to come in why don't I ask a question that we received regularly.

With the incidents of diphtheria and tetanus being so low why should we continue to vaccinate against those disease?

Candice Robinson: Yes. So it is true that these diseases are rare in the U.S. and this is likely due, in a large part, to the success of vaccination for these diseases. However these diseases have not been eradicated therefore without vaccination there is a possibility of infection.

The bacterium that causes tetanus is ubiquitous and is present in the soil. And while diphtheria is more prevalent outside the U.S., there could be some unreported cases here in the U.S.

Specifically because, like I mentioned earlier in the talk, physicians do not regularly consider this diagnosis and laboratories will not test for the organism unless specifically told to do so.

So again, while the incidents of these two diseases are low here in the U.S. we still require lifetime protection against both of these organisms.

Andrew Kroger: Thank you for that answer, Candice. We'll take the next question if there's one in the queue?

Coordinator: The next question comes from ()

(XXXXXXX): Yes, good - yes, I have a question. The question is have is that if a patient has Tdap, if we administer a Tdap to a patient like two dose and the patient is on a catch-up schedule and we give a Td at eight, seven, when the child is ready to go to middle school would you recommend that we give another Tdap? Did you hear me?

Candice Robinson: I'm sorry we - at the end of the question the sound kind of changed. Could you repeat the end of the question again?

(XXXXXX): Okay. We wanted to know if the child is on a catch-up schedule and we did Tdap at age seven when the child is ready to go to middle school at age 11 to 12 years old would you recommend that we give a Tdap, T-D-A-P or we give Td?

Candice Robinson: So if they received the dose of Tdap at age seven years and they're on a catch-up schedule then the next dose should be Td vaccine. And then when they go to middle school you just to finish out the primary series with Td vaccine. Only that one Tdap is necessary because they got it at seven years of age or older.

(XXXXXXX): Okay. And could you review the schedule for the Td because you were saying one first and then the second dose four weeks after. Could you review that, please?

Candice Robinson: Sure. Let me just get back to that in my notes. Yes, this is specifically for an adult or - let's say a person without a history of a primary series of DTaP. The preferred schedule is as follows, you would want the first dose to be a dose of Tdap.

(XXXXX): Okay.

Candice Robinson: The second dose in that series you would want to be a dose of Td given at least four weeks after the first dose. And then your third dose would be Td and it should be given at least six months after the second dose.

(XXXXXX): Okay. So...

Candice Robinson: Yes, at that point the primary series is considered complete and they would then receive Td boosters every ten years thereafter.

(XXXXXX): Thanks for that clarification.

Candice Robinson: You're welcome.

Andrew Kroger: Thank you. We'll take the next question in the queue?

Coordinator: Next question comes from ().

(XXXXXXX): Hi. Thank you guys for your presentation. If we know that the pertussis part of the DTaP and the Tdap wanes after at least five years why aren't we revaccinating or researching a new vaccine that lasts longer or protects them longer.

If we have household contacts that are infecting these infants that we can't protect with vaccines because they're too young why aren't we making a better recommendation?

Candice Robinson: Yes, so absolutely. Currently, the Tdap vaccine is FDA approved only for the single dose therefore any search recommendation at this time for further doses of Tdap would be considered an off-label use.

Now, the ACIP has reviewed this issue a couple times in the past as recently as October of 2014 and currently there are a couple of factors. First, the data suggests that revaccination would probably have a very limited effect on the burden of pertussis disease in the U.S. as a whole.

And many adults, we know, don't have their first of dose of Tdap. Our first dose Tdap vaccination and coverage rates are actually pretty low. So therefore, we're really focusing on getting the first dose into the adult population.

Secondly, the highest morbidity and mortality of pertussis is in infants - as you have pointed out. And there is a strategy in place for this age group. So the ACIP strongly supports and recommends focusing our efforts on

preventing pertussis in infants through the vaccination of pregnant women during each pregnancy as well as through vaccination of the household contacts during the women's first pregnancy.

CDC and ACIP concluded that the data do not favor general recommendation for a second dose of Tdap and therefore it is currently not a recommendation for universal second dose Tdap vaccination.

However, we are aware that the manufacturers of Tdap vaccines are collecting data on revaccination and they will be discussing these results with the FDA in the not too distant future. Currently the recommendation stands at one dose.

(XXXXX): Okay, thank you.

Andrew Kroger: Thank you very much. We'll take the next question.

Coordinator: Our next question comes from ().

(XXXXX): Okay, can you hear me okay?

Andrew Kroger: Yes.

Candice Robinson: Yes, we can hear you.

(XXXX): Okay. We are currently giving the BOOSTRIX vaccine, the Tdap vaccine and we - I have the insert from the medication itself with me right now, right here and it says there are no adequate or well controlled studies in pregnant women because animal production studies are not always predictive of human responses.

BOOSTRIX should not be given to a pregnant woman only if clearly needed. I'm personally not comfortable giving this vaccine to pregnant women. And all the studies you say you're only giving one Tdap but you're giving a pregnant woman a Tdap every time she's pregnant. I'm just really unclear with why we are doing that.

Candice Robinson: Sure. So a little bit earlier in the talk we kind of discussed some of the rationale behind the ACIP recommendations of Tdap in these women - in pregnant women, specifically.

So a couple of things, A the Tdap in the pregnancy does help to provide the infant with protection from pertussis in this group that has the highest morbidity and mortality from the disease.

Additionally, based on some of the previous work we do know that there has been no study that has assessed the safety of repeated doses of Tdap vaccine. However there is some data - reassuring data on two doses of Tdap.

And our previous experience with repeated doses of tetanus toxoid suggests no excess risk of adverse events. So given the benefit of vaccinating in this population and from the studies that the ACIP took into consideration without the evidence of increased risk of adverse events the ACIP felt comfortable making this recommendation.

Again, we are continuing to monitor this vaccination administration, this population and we're continuing to collect data on the safety in this population.

(XXXXX): Okay. So would this be considered as an off-label use then because the label itself does not necessarily recognize it as being safe for pregnancy because it

says, you know, there are no well controlled studies in pregnant women. So is this off-label? Should we have an order from a doctor to be able to give this?

Candice Robinson: Is an order from a doctor to be able to give this? That's a great question. Actually if you could email that question to our NIPINFO Website because NIPINFO@CDC.gov and we'll be able to give you more specific individual information regarding the administration.

(XXXX): Okay, thank you.

Andrew Kroger: Thank you. We'll take the next question in the queue.

Coordinator: This question comes from ().

(XXXXXX): Hi, yes. Can you hear me?

Andrew Kroger: Yes, we can hear you.

(XXXXX): This is just a follow-up on the Tdap for healthcare employees. So from my understanding it's a recommendation it's not a mandatory vaccination?

Candice Robinson: Yes. ACIP provides recommendations for vaccinations in certain populations but not regulations.

(XXXXX): Okay. Is that on the website? I know towards the end there was a website from the ACIP about all the updated recommendations on these vaccinations. Is that on there for the healthcare personnel?

Candice Robison: Yes. You can find all of these recommendations in the ACIP recommendations on the CDC Website.

(XXXXX): Okay, thank you.

Candice Robinson: Yes, okay.

Andrew Kroger: Thank you. We'll take the next question in the queue?

Coordinator: Next question comes from ().

(XXXX): Yes, good afternoon.

Andrew Kroger: Good afternoon.

Candice Robison: Good afternoon.

(XXXX): My question is when you're playing catch-up with a child seven to nine years of age and they need the tetanus and pertussis it was recommended they get a dose of Tdap, okay. Is that considered an off-label use of it?

Candice Robinson: Yes.

(XXX): Okay.

Candice Robinson: Tdap use in this age group seven to nine years is an off-label ACIP recommendation.

(XXXX): So I mean there is nothing else that we can give them other than...

Candice Robinson: Correct.

(XXX): Okay.

Candice Robinson: Exactly because all of the DTaP vaccines have a maximum age of six and the labels for the Tdap vaccines have a lower limit age of ten so this is an off-label recommendation.

(XXX): Okay, thank you.

Candice Robinson: You're welcome.

Andrew Kroger: We can take the next one in the queue.

Coordinator: The next question comes from ().

(XXX): Hi, can you hear me?

Candice Robinson: Yes.

Andrew Kroger: Barely, yes.

(XXX): Oh okay. My question has mostly been answered and it was regards to patients age seven through nine who had not had any previous DTaP vaccines. So we give one Tdap and that is considered adequate Pertussis immunity for these children?

Candice Robinson: Yes.

(XXX): Because the further the second two will be both Td, correct?

Candice Robinson: Correct, the second two will be both Td.

(XXX): Okay. And so they just start getting that one pertussis dose?

Candice Robinson: Correct.

(XXX): Okay, thank you so much.

Andrew Kroger: Thank you. Why don't we take one last question?

Coordinator: Okay. Our next question comes from ().

(XXXX): My question was previously answered, thank you.

Andrew Kroger: I think we have time for one more if we have another question.

Coordinator: Another question from ().

(XXX): Hi. My question is for Pentacel. If you inadvertently give just a DTaP and then the IPV part without mixing with the Hib what should you do next? Do you count the IPV and DTaP as valid or do you not?

Candice Robinson: So in that instance you can count the DTaP and IPV as valid however you would still need to give that child a dose of Hib vaccine since they would not have received the Hib in that case.

(XXX): Thank you.

Andrew Kroger: Thank you. That's all the time, thank you for your questions. That's all the time we can devote to them now. So we are going to have a Q&A session at 10:00 am Eastern time next Thursday August 27.

We will continue to stay on the line as long as we continue to receive questions up to one hour. So now let me repeat the CE information. For CE credits you can see the Website, www2A.CDC.gov/TCEonline.

The course number which is data specific is E as in Edward, C as in cat, 2064-081915. Please note that date specific extension. The verification code is DTAP7 with no space.

So write it down I'll repeat it, it's DTAP and then the numeral 7, just like the vaccine that we've talked about today the pediatric vaccines. That's the verification code. CE credit expires September 21, 2015,

For help with the online system available 8:00 am to 4:00 pm Eastern time please dial 1-800-41-TRAIN which corresponds to the number 1-800-418-7246 or you can email CE@CDC.gov.

You can email immunization questions to us if you did not get to ask them today and you cannot participate in the Q&A session next week. That email address is NIPINFO@CDC.gov and we'll try to respond to those as quickly as possible.

You can also call immunization questions to 1-800-CDC-INFO from 8:00 am to 8:00 pm Eastern time Monday through Friday. Additional resources that you can use include the Pink Book and the Website for the Pink Book is www.CDC.gov/Vaccines/Pubs/Pinkbook/index.html.

It's available online or you can purchase a hardcopy at the link for the Public Health Foundation Learning Resource Center. Our CDC vaccine homepage is www.CDC.gov/vaccines/default.htm.

Our resource guide for healthcare personnel is entitled CDC Immunization Resources for you and your Patients is listed at www.CDC.gov/Vaccines/ED/downloads/IMZ-Resources.PDF.

Follow us on Twitter for immunization news, information and resources for private and public healthcare personnel and that's @CDCIZLEARN on Twitter. So that concludes our program.

I want to thank Dr. Candice Robinson for the presentation covering our topic in great detail and for answering your questions. Thank you very much and have a great day from Atlanta. Good bye.

Coordinator: This concludes today's conference thank you for your participation you may now disconnect.

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